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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,516	11/14/2001	David A. Shafer	D6431	8007

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,516

Applicant(s)

SHAHER, DAVID A.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 8 and 23-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election with traverse of Group II, claims 7-22, species of claim 11(disposable tips), claim 13(piezoelectric pressure), claim 18 (rigid glass), claim 19(polynucleotides), claim 20 (total RNA) and claim 22 (direct fluorescent reagents) in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the examiner's assertion of performing the claimed processes by hand is unreasonable. It is further argued that the examiner's assertion that the claimed processes could be performed by hand is not reasonable. This is not found persuasive because the specification at page 2, line 4 up to page 5, line 16 states that "...hybridization arrays were commonly manufactured by hand or with limited automation..." See further the different methods taught in the different prior art at page 2, line 5 up to page 6, line 20 of the instant specification. Also, Figure 5.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 8 and 22-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

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Information Disclosure Statement

The listing of references in the specification (page 51, line 10 up to page 52, line 16) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities:

A. The numbers (8, 12, 13) at page 6 provides for confusion and ambiguity as for its designation. If these are the cited references, it is suggested that the full name of the reference be used in lieu of the numbers. Applicants are requested to check for the other numbers in the specification since they are too numerous to mention specifically.

B. U.S. Pat. No. 6,001,309 recited at page 5, line 15 is incorrect. There is no Patent issued with said numbers. Appropriate correction is required.

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The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and/or idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements and steps. See MPEP § 2172.01. The omitted elements are: e.g., a mechanical pump or piston in order to achieve the process steps of pressuring and/or touching. Cf. with Example 1. "The narrow opening of the tip" in step b lacks antecedent basis of support from step a. "The surface of the miniarray substrate" lacks antecedent basis of support from the preceding steps. It is not

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clear, within the claimed context, as to the step of "an action" effective to release the droplet.

B. In claim 9, the metes and bounds of the "more than one" row is indefinite as to the maximum limit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 9-10, 12-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Balch (U.S.6,083,763) or Lockhart et al (6,040,38).

Balch discloses at col. 13, line 61 up to col. 15, line 60 a robotic method for manufacturing microarrays (miniarray, as claimed). The method comprises depositing by a capillary tube (pipette-based dispensers, as claimed) an analyte reagent wherein the capillary is within a corresponding supply chamber,

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wherein each supply chamber is capable of supplying a liquid reagent to at least one corresponding capillary tube; and a positioning device for precisely positioning the array template and said capillary tubes with respect to said reaction substrate and depositing liquid reagents from said distal end of said capillary tubes onto said reaction substrate as biosites. See further Balch's disclosure at col. 25, lines 25-55 for fluorescent labeling of analytes; Example V, col. 37 for mRNA analysis, as the analyte. Since all the claimed elements are fully met by Balch the claimed invention is therefore anticipated by the Balch reference.

Lockhart basically discloses the same method steps as the claimed invention. See e.g., col. 21, line 15-25.

Claims 7, 9-10, 12, 15, 16, 18 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (5,807,522).

Brwon et al discloses at col. 3, line 23 up to col.4, line 59 a method of forming a microarray of analyte-assay regions on a solid support, where each region in the array has a known amount of a selected, analyte-specific reagent. The method comprises loading a solution of a selected analyte-specific reagent in a reagent-dispensing device having an elongate capillary channel (pipette-based dispensers as claimed) (i)

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formed by spaced-apart, coextensive elongate members, (ii) adapted to hold a quantity of the reagent solution and (iii) having a tip region at which aqueous solution in the channel forms a meniscus. The tip of the dispensing device is tapped against a solid support at a defined position on the support surface with an impulse effective to break the meniscus in the capillary channel, and deposit a selected volume of solution on the surface. The two steps are repeated until the desired array is formed. See further col. 6, line 64 up to col. 9, line 50 and the claims. Accordingly, the specific process steps of Brown fully meet the broad claimed process steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Balch or Lockhart or Brown in view of (Lange, abstract).

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Each of the Balch or Lockhart or Brown references is discussed, above. The references do not disclose a disposable tips dispensers. However, Lange discloses the use of a disposable pipette (see the abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a disposable unit in the method of any one of Balch or Lockhart or Brown as taught by Lange. A disposable dispenser unit would obviously produce a contamination free device for pipetting liquids. One would have been motivated to use a disposable unit since contaminants can produce false background during hybridization.

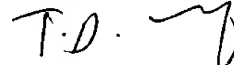
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
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tdw
March 10, 2003